

REMARKS

This responds to the Office Action dated January 27, 2006, and the references cited therewith.

Claims 1, 4 are amended; claims 1 -20 are now pending in this application.

§112 Rejection of the Claims

Claims 4, 8-14 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention. The claims were amended to clarify the subject matter therein. The amendments make express of what was implicit in the claims as originally worded. Reconsideration and allowance of claims 4, 8-14 are respectfully requested.

§102 Rejection of the Claims

Claims 1, 3-4, 6-10, 12, 14-16 and 19-20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Huepenbecker et al. (U.S. Patent No. 6,289,251). Applicant respectfully traverses the rejection.

In order for a prior art reference to anticipate under 35 U.S.C. § 102, “every element of the claimed invention must be identically shown in a single reference.” (emphasis added). *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In addition, in order to anticipate the elements in the single reference “must be arranged as in the claim under review.” *Id.*, (quoting *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1948)). Finally, “the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.” *Akzo N.V. v. United States Int’l Trade Comm’n*, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1989).

Applicant cannot find all of the elements of the claims in Huepenbecker. For instance, Applicant cannot find in Huepenbecker a recessed portion recessed away from the bottom surface of the tine when the tine is disposed in the second collapsed position, as recited in claim

1 and 14, or forming a first recessed portion along the lead body along the tine interface portion including recessing the first recessed portion away from the bottom surface when the one or more tines are disposed in the second collapsed position, as recited in claim 15. Applicant further cannot find in the reference the first portion along the tine interface second having a first cross-sectional shape that is different than a second cross-sectional shape, as recited in claim 8. Claims 3 – 4, 6 – 7 also include the limitations of claim 1, claims 9-10, 14 include the limitations of claim 8, and claims 16, 19-20 include the limitations of claim 15 and are likewise not anticipated by Huepenbecker.

Applicant notes that Huepenbecker does not include any figures illustrating tines in a collapsed position. According to the Office Action at Page, “when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine.” Applicant respectfully submits that Huepenbecker does not enable such a statement, and therefore the Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Applicant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Applicant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the alternative, withdrawal of this assertion from the rejection.

Furthermore, the Office Action states at Page 3 “the tines necessarily have a second collapsed position because the tines are formed of a flexible material such that the tines folds/collapse against the lead body during insertion into the patient.” This assertion appears to contradict the Office Action assertion discussed in the previous paragraph. Furthermore, Applicant respectfully submits that Huepenbecker does not enable such a statement, and therefore the Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Applicant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Applicant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the alternative, withdrawal of this assertion from the rejection.

According to the Office Action, “lead includes two recessed portions, as indicated in Fig. 4”. Page 3, Office Action. Applicant respectfully traverses the assertion. Applicant notes that Huepenbecker does not state the drawings are to scale. “It is well established that patent

drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.” *Hockerson-Halberstadt v. Avia Group International, Inc.*, 222 F.3d 951, 956 (citing *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977)). Applicant respectfully submits that Huepenbecker fails to anticipate claims 1, 3-4, and 6 – 10 because the specification does not establish all of the elements, and is not an enabling reference.

With respect to claims 3, 9, 19 - 20, the Office Action states at Page 4, “the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.” While it is unclear on what the Office Action relies to make such a statement, Applicant cannot find support in the specification for such an assertion. Further, the specification fails to state the drawings are to scale. Applicant submits that Huepenbecker does not anticipate claims 3, 9, 19-20, and is not an enabling reference. Reconsideration and allowance of claims 3, 9, 19 – 20 are respectfully requested.

The Office Action further states on Page 4, “it appears from Figure 4 that the cross-sectional area at the lead distal end . . . is approximately the same as the cross-sectional area of the tine coupling portion. Accordingly, the cross-sectional area of the tine coupling area is necessarily ‘less than 10% smaller’ than the cross-sectional area of the lead distal end.” With respect to claims 6 and 7, the Office Action states at page 4 “the length of the first recessed portion is less than the tine length,” and “[a]s shown in Fig. 4, the diameters of the spacer 34, the first recessed portion, and the second recessed portion are each different from one another.” With respect to claim 8, the Office Action states at Page 5, “the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.” Applicant cannot find support in the specification for these assertions. Further, the specification fails to state the drawings are to scale. Still further, it is unclear how these conclusions can be reached when Figure 4 only illustrates a longitudinal cross-section. Reconsideration and allowance of claims 4, 6, 7, and 8 are respectfully requested.

Claims 1, 3-4, 6-10, 12, 14-16 and 19-20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Laske et al. (U.S. Patent No. 5,807,399). Applicant cannot find all of the

elements of the claims in Laske. For instance, Applicant cannot find in Laske a recessed portion recessed away from the bottom surface of the tine when the tine is disposed in the second collapsed position, as recited in claim 1 and 14, or forming a first recessed portion along the lead body along the tine interface portion including recessing the first recessed portion away from the bottom surface when the one or more tines are disposed in the second collapsed position, as recited in claim 15. Applicant further cannot find in the reference the first portion along the tine interface second having a first cross-sectional shape that is different than a second cross-sectional shape as recited in claim 8. Claims 3 – 4, 6 – 7 also include the limitations of claim 1, claims 9–10, 14 include the limitations of claim 8, and claims 16, 19–20 include the limitations of claim 15 and are likewise not anticipated by Laske.

Applicant notes that Laske does not include any figures illustrating tines in a collapsed position. According to the Office Action at Pages 5 and 6, “when the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine.” Applicant respectfully submits that Laske does not enable such a statement, and therefore the Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Applicant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Applicant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the alternative, withdrawal of this assertion from the rejection. In contrast, the pliant tines of Laske may be disposed within any portion of the lead body, because “the tines [are] formed of a soft, pliant material.” Page 5, Office Action.

With respect to claims 3, 9, 19 – 20, the Office Action states at Page 6, “the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.” While it is unclear on what the Office Action relies to make such a statement, Applicant cannot find support in the specification for such an assertion. Further, the specification fails to state the drawings are to scale. Applicant submits that Laske does not anticipate claims 3, 9, 19–20, and is not an enabling reference. Reconsideration and allowance of claims 3, 9, 19 – 20 are respectfully requested.

The Office Action further states on Page 6, “it appears from Figure 5 that the cross-sectional area at the lead distal end is slightly larger than the cross-section area of the tine coupling portion. Examiner considers the cross-sectional area of the tine coupling area to be

approximately “less than 10% smaller” than the cross-sectional area of the lead distal end.” The examiner is using personal knowledge, and applicant requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Applicant cannot find in the specification of Laske that the cross-sectional area of the tine coupling area to be less than 10% smaller. Further, the specification fails to state the drawings are to scale. Applicant submits that Laske does not anticipate claim 4, and is not an enabling reference.

With respect to claims 6 and 7, the Office Action states at pages 6 and 7, “the length of the first recessed portion is less than the tine length,” and “[a]s shown in Fig. 5, the diameters of the sheath 122, the first recessed portion, and the second recessed portion are each different from one another.” With respect to claim 8, the Office Action states at Page 8, “the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion.” Applicant cannot find support in the specification for these assertions. Further, the specification fails to state the drawings are to scale. Still further, it is unclear how these conclusions can be reached when Figure 5 only illustrates a longitudinal cross-section. Reconsideration and allowance of claims 4, 6, 7, and 8 are respectfully requested.

§103 Rejection of the Claims

Claims 2, 5, 11, 13 and 17-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Huepenbecker et al. (U.S. Patent No. 6,289,251) in view of Alferness et al. (U.S. Patent No. 5,531,781). Applicant respectfully traverses the rejection.

To establish a *prima facie* case of obviousness, a prior art reference must teach all of the claim limitations. MPEP § 2143, *In re Royka*, 490 F.2d 981 (CCPA 1974). Applicant submits that the rejection has not established a case of obviousness since the rejection has not shown that each element is taught by the cited patents. Applicant incorporate the above-discussion with respect to the independent claims, and how Huepenbecker fails to establish all of the elements. Alferness does not supply the missing elements.

Notwithstanding that all of the elements cannot be found in the cited references, the Office Action fails to provide a legally sufficient motivation to combine the references. The Office Action states at page 8 “it would have been obvious . . . in order to ensure that lead body

is sufficient strong during implantation.” Applicant respectfully submits that this statement is unsupported by the cited references. Applicant respectfully submits that Huepenbecker nor Alferness do not enable such a statement, and therefore the Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Applicant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Applicant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the alternative, withdrawal of this assertion from the rejection. Furthermore, it is unclear why Huepenbecker would be in need of such a selective modification. Reconsideration and allowance of claims 2, 5, 11, and 17 are respectfully requested.

Claims 2, 5, 11 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Laske et al. (U.S. Patent No. 5,807,399). Claims 13 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Laske et al. (U.S. Patent No. 5,807,399) in view of Alferness et al. (U.S. Patent No. 5,531,781).

Applicant submits that the rejection has not established a case of obviousness since the rejection has not shown that each element is taught by the cited patents. Applicant incorporates the above-discussion with respect to the independent claims, and how Laske fails to establish all of the elements. Applicant submits that Alferness does not supply the missing elements.

Notwithstanding that all of the elements cannot be found in Laske (or Alferness), the Office Action fails to provide a legally sufficient motivation to combine the references. The Office Action states at page 9 “it would have been obvious . . . to modify the external groove 152 of Laske et al. such that it only extends around a portion of the perimeter of the lead body (so long as the sheath 122 may be readily separated when force is applied thereto) in order to ensure that sheath 122 is sufficiently strong during implantation.” Applicant respectfully submits that this statement is unsupported by the cited references. Applicant respectfully submits that Laske does not enable such a statement, and therefore the Office Action is relying on either Official Notice, or the personal knowledge of the Examiner. Applicant hereby requests an affidavit under 37 CFR 1.104(d)(2), or removal of the assertion. Applicant traverses the Official Notice and respectfully requests a patent under MPEP § 2144.03 to support the assertion, or in the

alternative, withdrawal of this assertion from the rejection. Furthermore, when considered as a whole, Laske teaches away from making the selective modification as suggested in the Office Action.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Element 152 is to create a weakened portion. Prior art that teaches away from the claimed combination is a factor cutting against a finding of motivation to combine or modify the prior art. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path the applicant took. *In re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994); *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (C.C.P.A. 1969); *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 243, 245 (C.C.P.A. 1963).

To use hindsight reconstruction and say element 152 could be made to extend only partially around the perimeter to strengthen the lead is opposite of what the reference describes, and would frustrate the purpose of element 152, that is, to allow the lead to separate. Element 152 is designed to allow for a weakened portion of the lead, which teaches away from trying to use the same element to make the lead stronger.

Reconsideration and allowance of the claims are respectfully requested.

Documents Cited But Not Relied Upon For This Office Action

Applicant need not reach the assertions of similarity stated in Paragraph 11, Pages 11 and 12 of the Office Action, because these patents are not made part of the rejections in this Office Action. Applicant is expressly not admitting to these assertions.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By their Representatives,

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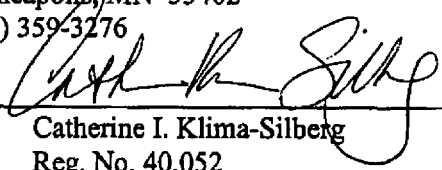
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 26 day of May, 2006.

Name

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